REMARKS

Claims 1-20, 23-36, and 38 are pending in the application.

Claims 1-10 and 13-15 are rejected under § 102(b).

Claims 11-12 are rejected under § 103(a).

Claims 16-20, 23-36 and 38 are indicated as being allowed.

As will be explained in more detail hereinafter, claim 1 requires at least the following four elements: (1) an attachment portion adapted for attachment to a wall of the heart or a blood vessel; (2) that the end of the conduit/cannula is attachable to the attachment portion; (3) that the end of the conduit/cannula is contained within the enclosure; and (4) that the attachment portion is separable from a remainder of the enclosure. Each of these will be treated individually below.

§ 102(b) REJECTIONS

Claims 1-10 and 13-15 are rejected under § 102(b) as unpatentable for being anticipated by Sherman et al. '159 ("Sherman"). The Examiner continues to characterize Sherman et al. as disclosing "a ring or 'attachment portion' or 'sewing cup' 26 separable from enclosure 12." Applicant respectfully disagrees with this characterization.

More importantly, however, even if the rack 26 were separable, there are several other limitations recited in claim 1 which are also not shown in Sherman, et al., and which the Examiner has not yet mentioned specifically. In particular, claim 1 also requires (1) that the separable attachment portion be attachable to the tissue, (2) that the end of the conduit (i.e., cannula) attaches to the attachment portion, and (3) that the end of the conduit is contained within the enclosure. Each of these limitations is treated in more detail below.

I.

Claim 1, part a, recites that the attachment portion is "adapted for attachment to a wall of said heart or blood vessel." In this regard, claim 1 is amended herein to make even more clear that which was already inherently required-- that the attachment portion remains attached to the tissue. Specifically, claim 1 now reads:

> ...said attachment portion separable from a remainder of said enclosure such that said attachment portion remains attached to said wall of said heart or blood vessel once attached thereto;

The rack 26 in Sherman, et al. is not attachable to the tissue such that it remains attached to the tissue after the inner tubular member 14 is removed. The rack 26, and cooperating annular needle 36, merely apply the sutures to the tissue. The rack 26 never becomes attached to the tissue. That would be contrary to and inconsistent with the teaching of the patent.

For example, at column 10, lines 64-67, Sherman, et al. specifically describe a "needle removal mechanism which is designed to remove or eject needle 36 from the annular needle passage upon one complete rotation of the needle." (Emphasis added.) Thus, neither the rack 26 nor the annular needle 36 ever become attached to the tissue.

There is no sewing cuff or any other "attachment portion" consistent with claim 1 which is described or taught in Sherman, et al. as being attached to the tissue by the purse string sutures. Rather, the purse string sutures are applied and used to attach **only** the end of the cannula. The purse string suture device is not designed to attach a sewing cuff. Instead, the device is designed to attach the cannula directly to the tissue without using a sewing cuff. Therefore, no part of the device in Sherman et al. is attachable to the tissue.

II.

Claim 1 has always recited that the end of the conduit was "attachable to said attachment portion." To even further clarify the inherent result of attaching the end of the conduit to the attachment portion, claim 1 is amended herein as follows:

> a conduit having a first end attachable to said attachment portion, said first end contained within said enclosure, wherein said first end of said conduit is attachable to said wall of said heart or blood vessel via said attachment portion.

Thus, as amended, the end of the conduit is attached to the tissue via attachment to the attachment portion. In Sherman, et al., the end of the cannula is not attached to the rack 26 (which has been characterized as the "attachment portion").

As can be seen in columns 15 and 16, the end of the cannula is inserted through the outer tubular member 12 into an incision in the tissue, and is retained there by the purse string sutures. The cannula is never attached to the rack 26, or any other part of the "enclosure." By the time the cannula is inserted, the rack 26 has already been withdrawn, along with the inner tubular member 14. In fact, the rack 26 must be withdrawn even before the incision can be made to insert the cannula. This is another reason why the rack 26 cannot be the claimed "attachment portion."

III.

If the rack 26 is characterized as the "attachment portion," then, to be consistent with claim 1, the inner tubular member 14 must be the "enclosure." As recited in claim 1, the end of the cannula is "contained within said enclosure." Therefore, the end of the cannula in Sherman, et al. must be "contained within" the inner tubular member 14. This is not the case. Instead, Sherman, et al. explains that the end of the cannula is inserted into the outer tubular member 14 **after** the inner tubular member 12 is removed.

As explained above, referring to columns 15 and 16 in the patent, the end of the cannula is inserted through the outer tubular member 12 into an incision in the tissue, and is retained there by the purse string sutures. By the time the cannula is inserted, the rack 26 has already been withdrawn, along with the inner tubular member 14. In fact, the rack 26 must be withdrawn even before the incision can be made to insert the cannula.

Therefore, the inner tubular member is not the claimed "enclosure." As above, this is yet another reason why the rack 26 cannot be the "attachment portion" recited in claim 1.

IV.

Finally, Applicant respectfully reiterates that the rack 26 is not "separable" from the inner tubular member 14. Nothing in Sherman, et al. teaches separating the rack 26 from the inner tubular member 14. In fact, this is contrary to the teaching in Sherman, et al.

The Examiner cites to Figures 4, 12, 16a and 16b and various text in columns 1, 8, 9, 10, 13, 14, 16 and 17 to support the argument that rack 26 is "separable." Applicant has reviewed each of the drawing figures, and has reviewed all of the text referenced by the Examiner.

Respectfully, none of the drawings and none of the text indicate in any way that the rack 26 is separable from the inner tubular member 14. Rather, all of the text and drawings indicates that the rack 26 is an integral, non-detachable part of the apparatus.

It seems to the Applicant that certain of the drawings referred to are being misinterpreted because exploded views and "cut-away" sections of the apparatus. For example, as can be determined from the "Brief Description of the Drawings" (see columns 5 and 6), Figure 4 is an "exploded view" of the tubular structure illustrated in Figure 2. In particular, just because the rack 26 is shown apart from other components of the device, does not in mean that this is a

"detachable" or "separable" part of the structure. It is merely shown like this because that is the nature of an "exploded view."

Each "exploded" part of the apparatus is not detachable. The apparatus would have to be disassembled to separate the rack 26 from the rest of the structure. Consequently, there is no way in which the rack 26 can be detached, separated, or otherwise removed from the end of the inner tubular member 14, short of disassembling the device entirely, and this is not consistent with either the present invention, as recited in claim 1, or the description of the operation of the purse string suture apparatus in Sherman, et al.

It is believed that the operation of the purse string suture device, as it is described in Sherman et al., makes it clear that the rack 26 is (1) not separable part, (2) is not attachable to the tissue, (3) is not attached to the cannula, and (4) that the end of the cannula is not "contained within" the inner tubular member 14-- all of which are recited in claim 1.

At column 15, lines 30-42, and also in the first two lines of column 16, Sherman et al. provide an overview of the operation of the described "Automatic Purse String Suture Device."

Beginning with the suturing operation, the first step is to complete the purse string suture using the device described in the patent, e.g., by pressing the end of the applicator against the tissue to be sutured and rotating the opposite end of the device-- which rotates the suture needle, as supported by the rack 26, which threads the suture string through the tissue.

After the suture is applied, the inner tubular member 14 (and the rack 26 with it) is removed from the outer tubular member 12. Next, a tool for creating an incision is inserted into the outer tubular member 12 and an incision is created in which to insert a cannula. (See Col. 16, lns. 1-2.) Afterwards, the incision tool is removed from the outer tubular member 12 and a

cannula is inserted therein for attachment to the tissue. The end of the cannula is inserted into the incision, and the suture is tightened to seal against the cannula. The suture is then tied off and the outer tubular member 12 is removed from the patient.

At the completion of the operation described above, no portion of the purse string suture apparatus remains in the patient, and only the end of the cannula is attached to the tissue. The patent never describes or teaches any portion of the purse string suture apparatus which is separable, or which is attached to the tissue, or which is attached to the cannula.

§ 103(a) REJECTIONS

Claims 11-12 are rejected under § 103(a) as unpatentable for being obvious over Sherman in view of Leahy et al. '409 ("Leahy"). Claims 11 and 12 depend ultimately from claim 1, and are believed patentable because claim 1 is believed patentable.

ALLOWED CLAIMS

Claims 16-20, 23-36 and 38 are indicated as being allowed.

CONCLUSIONS

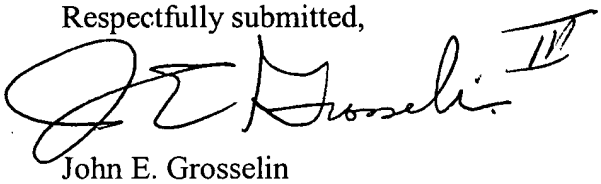
In order to anticipate claim 1, the rack 26 would have to be attached to the tissue, separated from the inner tubular member 14 leaving the rack 26 attached to the tissue, and then attached to the end of the cannula. Additionally, the end of the cannula would have to be contained within the inner tubular member 14.

Specifically, claim 1 requires (1) an attachment portion adapted for attachment to a wall of the heart or a blood vessel; (2) that the attachment portion is separable from a remainder of the enclosure; (3) that the end of the conduit/cannula is contained within the enclosure; and (4) that

the end of the conduit/cannula is attachable to the attachment portion. For all of the reasons set forth in detail above, Sherman, et al. does not disclose or teach any of these limitations.

Therefore, claims 1 through 15 are patentable over Sherman, et al. and all of the prior art of record. Accordingly, reconsideration and allowance of claims 1 through 15 are respectfully requested.

Respectfully submitted,



John E. Grosselin
Registration No. 38,478
BUCHANAN INGERSOLL
PROFESSIONAL CORPORATION
One Oxford Centre, 20th Floor
301 Grant Street
Pittsburgh, PA 15219-1410
Attorneys for Applicant

412-562-1370